

Exhibit 4

(Filed Under Seal)

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF ARIZONA
3 * * * * *
4
5 In Re Bard IVC Filters Products
6 Liability Litigation
7
8 No. MD-15-02641-PHX-DGC
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10 * * * * *
11
12 DO NOT DISCLOSE - SUBJECT TO FURTHER
13 CONFIDENTIALITY REVIEW
14
15 VIDEOTAPED DEPOSITION OF JOSHUA RIEBE, MD
16
17
18 TAKEN AT: Radisson Hotel
19 LOCATED AT: 2040 Airport Drive
20 Green Bay, WI
21
22 April 4, 2017
23 10:09 a.m. to 2:15 p.m.
24 REPORTED BY ANITA K. FOSS
25 REGISTERED PROFESSIONAL REPORTER
* * * * *

1 yes.

2 Q. For example, have you ever put in any --
3 any Cook products before?

4 A. I have put in Cook products before.

5 Q. Have you ever put in any Bard products
6 before?

7 A. Yes.

8 Q. Any other types of filters that you
9 recall implementing?

10 A. Vena Tech. I don't know the major
11 corporation, but I recall that name as well.

12 Q. Have you ever been a consultant for any
13 of the IVC filter companies?

14 A. No.

15 Q. Have you ever been involved in any type
16 of studies involving IVC filters?

17 A. No.

18 Q. When you were in medical school, I assume
19 that you learned risk-benefit profiles for IVC
20 filters; is that correct?

21 A. Yes.

22 MS. DAVIS: Object to the form.

23 BY MR. GOLDENBERG:

24 Q. Okay. And can you tell me what -- first
25 of all, what is a risk-benefit profile?

1 MS. DAVIS: Object to the form.

2 THE WITNESS: Can you repeat that? I was
3 distracted.

4 BY MR. GOLDENBERG:

5 Q. Sure. That's okay. Would you agree that
6 you need complete and accurate information
7 regarding a filter from the manufacturer to help
8 conduct a risk-benefit analysis?

9 A. Yes.

10 MS. DAVIS: Object to the form.

11 BY MR. GOLDENBERG:

12 Q. And if there are risks that are not
13 disclosed or the true risks are not disclosed, then
14 you cannot conduct a -- conduct a proper
15 risk-benefit analysis for the patient; right?

16 A. Yes.

17 MS. DAVIS: Object to the form.

18 BY MR. GOLDENBERG:

19 Q. Is part of that analysis determining
20 whether a patient should receive a permanent or
21 retrievable filter?

22 A. Can you be more specific?

23 Q. Sure. When you're evaluating a specific
24 patient and implanting a specific device in a
25 patient, would that -- would part of that analysis

1 higher failure rates than other devices?

2 MS. DAVIS: Object to the form.

3 THE WITNESS: Yes.

4 BY MR. GOLDENBERG:

5 Q. Would you want to know if the rates of
6 certain adverse events are substantially higher
7 from one filter versus another?

8 A. Yes.

9 MS. DAVIS: Object to the form.

10 BY MR. GOLDENBERG:

11 Q. Would you want to know if the company had
12 concerns about the efficacy of its own filter?

13 A. Yes.

14 MS. DAVIS: Object to the form.

15 BY MR. GOLDENBERG:

16 Q. Would you want to know if a newer, safe
17 filter was available for use?

18 A. Yes.

19 Q. And by the way, if there are objections,
20 and there inevitably will be, we just need to make
21 sure we don't talk over each other. So she's
22 allowed to object, but you can continue to give
23 your answer, okay?

24 A. Okay.

25 Q. All right. Would you want to know if

1 Bard itself internally deemed the Recovery filter
2 to have unacceptable risks?

3 A. Yes.

4 MS. DAVIS: Object to the form.

5 BY MR. GOLDENBERG:

6 Q. Would you want to know if Bard, even
7 today, does not understand the root cause of why
8 its filters are migrating?

9 MS. DAVIS: Object to the form.

10 THE WITNESS: Yes.

11 BY MR. GOLDENBERG:

12 Q. Would you want to know if they, even
13 today, did not understand the root cause of why
14 their filters are perforating?

15 A. Yes.

16 MS. DAVIS: Object to the form.

17 BY MR. GOLDENBERG:

18 Q. Or tilting?

19 A. Yes.

20 MS. DAVIS: Same objection.

21 BY MR. GOLDENBERG:

22 Q. Or fracturing?

23 A. Yes.

24 MS. DAVIS: Same objection.

25 BY MR. GOLDENBERG:

1 Q. Would you want to know if a company did
2 not have a good understanding of long-term
3 performance of its retrievable filters?

4 A. Yes.

5 MS. DAVIS: Object to the form.

6 BY MR. GOLDENBERG:

7 Q. Would you want to know if a company's
8 lack of understanding of the dynamics of the vena
9 cava impacted its ability to test the filter?

10 A. Yes.

11 MS. DAVIS: Object to form.

12 BY MR. GOLDENBERG:

13 Q. Would these things we just discussed
14 inform your risk-benefit analysis?

15 MS. DAVIS: Object to the form.

16 THE WITNESS: I don't understand the
17 phrasing of that question.

18 BY MR. GOLDENBERG:

19 Q. Sure. The things that you mentioned that
20 you would like to know, if you did know those
21 things, would that be helpful for you to discuss a
22 risk-benefit analysis?

23 MS. DAVIS: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. GOLDENBERG:

1 Q. Okay. And they would be important in
2 terms of looking at patient safety; right?

3 A. Yes.

4 MS. DAVIS: Object to the form.

5 BY MR. GOLDENBERG:

6 Q. Would you expect a filter to be properly
7 tested for safety prior to introduction for the
8 market for use in human beings?

9 A. Yes.

10 Q. Do you know what beta testing is?

11 A. I've heard the term. I don't know the
12 specifics.

13 Q. Okay. What is your understanding of what
14 beta testing is?

15 A. I know it's a test that exists.

16 Q. You don't know how it works?

17 A. I don't know the specifics. I've heard
18 the term.

19 Q. I'll just move on. Okay. We talked a
20 little bit about sales reps, but I just want to
21 make sure that I've exhausted this, and I'll move
22 on quickly, okay. The -- I just want to make sure,
23 do you interact with sales reps from companies
24 whose filters you use, even today?

25 A. I don't understand how you phrased it.

1 centered upon deployment."

2 BY MR. GOLDENBERG:

3 Q. That's good enough. And if you could,
4 I'm looking at the top of this exhibit, and this
5 is -- do you see that it's from a Janet Hudnall to
6 a David Rauch?

7 A. Can you point?

8 Q. I can. Right there.

9 A. Yes.

10 Q. And the date of this is February 26,
11 2004?

12 A. Yes.

13 Q. All right. You can move on to the next
14 exhibit. Would you have expected Bard to tell you
15 if they were concerned about migration problems to
16 the point that they were going to actually put that
17 particular filter on hold? In other words, a
18 silent recall?

19 MS. DAVIS: Objection to the form.

20 THE WITNESS: I'm not sure.

21 BY MR. GOLDENBERG:

22 Q. So if this company was so concerned about
23 migration that it was considering putting it on
24 hold, in other words, recalling it, you wouldn't
25 want to know that as a doctor?

1 MS. DAVIS: Objection to the form.

2 THE WITNESS: I would want to know that.

3 BY MR. GOLDENBERG:

4 Q. Okay. And would you expect Bard to
5 understand the root cause of why it would be
6 migrating and causing deaths?

7 MS. DAVIS: Objection to the form.

8 THE WITNESS: I don't know that.

9 (Exhibit 917 marked for identification.)

10 BY MR. GOLDENBERG:

11 Q. I'm going to show you Exhibit No. 917.
12 I'll just represent to you that this was a
13 memorandum from a Doug Uelmen, E-U-L-A-N, February
14 13, 2004, regarding a filter meeting of
15 February 12th of 2004. And if you could, I'd like
16 you to turn to the third page of this exhibit. And
17 on number eight.

18 A. Yes.

19 Q. I'll just represent -- I'll just first
20 represent to you that there was a meeting that this
21 represents. And if you go down to number eight, if
22 you could just read that out loud, please.

23 A. Number eight. "The team discussed a
24 threshold level for migration and agreed that if a
25 migration requiring surgical intervention is

1 confirmed during the course of this investigation,
2 the Recovery filters will be placed on hold pending
3 the outcome of the investigation."

4 MS. DAVIS: Objection, form and
5 foundation.

6 BY MR. GOLDENBERG:

7 Q. So if Bard determined that migration was
8 a significant problem, you would want to know that
9 as a doctor, wouldn't you, to know that they were
10 putting this on hold pending an outcome of an
11 investigation?

12 MS. DAVIS: Objection to the form.

13 THE WITNESS: Yes.

14 BY MR. GOLDENBERG:

15 Q. Okay. If we turn to the next page, we
16 already talked about you indicating that you would
17 want to understand if Bard did not understand the
18 root cause. Could you read number nine, please?

19 A. Number nine. "Coordinate the review of
20 all data to determine root cause/most probable
21 cause using application problem-solving tools. A
22 meeting will be scheduled to conduct this review,
23 the time and place to be determined during a
24 subsequent team meeting. Attendees will include
25 the BPV investigation team along with" --

1 Q. That's okay. All right.

2 MS. DAVIS: Object to form.

3 BY MR. GOLDENBERG:

4 Q. And again, the date of this was
5 February 12th of 2004; do you see that on the
6 front?

7 A. Yes.

8 Q. Okay. Were you ever notified by anyone
9 at Bard that as of May -- I'm sorry, as of
10 April 7th of 2005, that they were going to be
11 discontinuing this product?

12 A. I was not.

13 Q. Would you have wanted to know that?

14 A. Yes.

15 Q. And why?

16 A. Yes.

17 (Exhibit 918 marked for identification.)

18 BY MR. GOLDENBERG:

19 Q. I'm showing you Exhibit No. 918. And
20 I'll just represent to you that this is an e-mail
21 from a Jack Sullivan, who was in sales, to a Janet
22 Hudnall, who was the director of marketing. And
23 the subject says "FAQ and answers." Do you see
24 that at the top?

25 A. Yes.

1 Q. And the date of this is 7/21/2005?

2 A. Yes.

3 Q. Okay. I'm just going to come down to the
4 part where it says "lastly." And do you see where
5 it says -- I'm just going to read this. It says,
6 "Lastly, it was a little weird being on calls with
7 Sean today and watching him sell the removability
8 of Recovery when I know we aren't going to have it
9 for much longer." Do you see that?

10 A. Yes.

11 Q. Then it says, "Is there anything we can
12 do now to help these guys? They are out trying to
13 hit a number, and we will be changing the device
14 soon." Do you see that?

15 A. Yes.

16 Q. Move to the next one. And you were not
17 aware of that; correct?

18 A. Correct.

19 Q. I've asked you this before, but I'm going
20 to ask a little different way. Would you have
21 expected Bard to have done a safety study on the
22 Recovery filter?

23 MS. DAVIS: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. GOLDENBERG:

1 Q. And why would that be important to you?

2 A. We like to use safe equipment on our
3 patients.

4 (Exhibit 919 marked for identification.)

5 BY MR. GOLDENBERG:

6 Q. Showing you what's been marked 919. And
7 I'll just represent to you that this is something
8 called internal question and answer. It says C.R.
9 Bard Recovery vena cava filter, version August,
10 2004. Do you see that?

11 A. Yes.

12 Q. And I'm just going to -- it says on the
13 top, it says, "Internal Q and A to be used,
14 approved by approved corporate spokespeople to
15 respond consistently to inquiries from media. Not
16 to be handed out externally to any audiences." Do
17 you see that?

18 A. Yes.

19 Q. Did I read that correctly?

20 A. Yes.

21 Q. I'm going to turn to page 3 of this. And
22 if you could read number six for us, please.

23 MS. DAVIS: Object to the form.

24 BY MR. GOLDENBERG:

25 Q. The question and the answer.

1 know that the reports of death, filter migration,
2 IVC perforation and filter fracture with Recovery
3 were four and even sometimes five times higher than
4 all other filters on the market?

5 MS. DAVIS: Objection, form, lack of
6 foundation.

7 THE WITNESS: Can you rephrase that?

8 BY MR. GOLDENBERG:

9 Q. Sure. Would it have been important for
10 Bard to tell you that their filters were
11 fracturing, migrating, and killing people at four
12 to five times greater rates than all other filters
13 on the market?

14 MS. DAVIS: Objection, form, lack of
15 foundation.

16 THE WITNESS: Four and five times a small
17 number is still a small number. However, absolute
18 data and rigorous analysis of the numbers would be
19 important, yes.

20 BY MR. GOLDENBERG:

21 Q. And so you would expect Bard to analyze
22 those and at least come to a root cause analysis,
23 wouldn't you?

24 A. Yes.

25 MS. DAVIS: Object to the form.

1 BY MR. GOLDENBERG:

2 Q. And you would want to know what the root
3 cause analysis is so you could help make an
4 understanding to the patient of what the safety of
5 this device would be?

6 A. Yes.

7 MS. DAVIS: Objection to the form.

8 (Exhibit 921 marked for identification.)

9 BY MR. GOLDENBERG:

10 Q. I'm showing you Exhibit 921. And you
11 indicated that you were interested in seeing
12 numbers. This is a memo on August 3rd of 2005, so
13 within a couple months of the time you actually
14 inserted the filter into my client. And this is
15 called IVC Recovery Filter Adverse Events Executive
16 Summary; do you see that?

17 A. Yes.

18 Q. Okay. And do you see that actually lists
19 all the different migrations and then what happened
20 from those migrations?

21 A. Yes.

22 Q. Okay. And do you see that there's
23 deaths, and there's also everything from migration
24 of the filter encased in large thrombi, to
25 fatalities?

1 A. Yes.

2 MS. DAVIS: Objection to the form and
3 lack of foundation to all these questions regarding
4 this Exhibit 941.

5 BY MR. GOLDENBERG:

6 Q. If you could, I'd like you to look at the
7 chart where it says "compare MAUDE data for IVC
8 filter fatalities." Do you see that?

9 A. Yes.

10 Q. And do you see that the SNF, which I'll
11 represent to you is the Simon Nitinol filter that
12 was the permanent filter that preceded Recovery by
13 Bard, how many fatalities were there with the SNF?

14 MS. DAVIS: Same objection.

15 THE WITNESS: It's reported as
16 zero percent.

17 BY MR. GOLDENBERG:

18 Q. Okay. And migration, what is it reported
19 as?

20 A. 0.0027 percent.

21 Q. So that would be less than one percent;
22 correct?

23 A. Correct.

24 Q. All right. And under Recovery, what's
25 the percentage of fatalities?

1 next page, excuse me, under B. I'm sorry, so
2 it's -- there's A and B, do you see that at the top
3 there?

4 A. Yes.

5 Q. Okay. Under the small B, if you could
6 read that, please.

7 A. "The two independent data sets, MAUDE
8 report rates and bench testing results, contain
9 significant signals regarding vena cava filter
10 performance related to migration."

11 Q. Were you aware of that before you
12 inserted this into my client?

13 A. No.

14 MS. DAVIS: Same objections.

15 BY MR. GOLDENBERG:

16 Q. Under the large B, could you read that
17 for me, please?

18 A. "The independent consultant's report
19 concluded that the data and his analysis provided
20 two significant signals that further investigation,
21 particularly in relation to migration and fracture,
22 is urgently warranted. The consultant, however,
23 also cautioned that given the multiple known flaws
24 in the data available, this analysis is
25 insufficient to demonstrate conclusively that any

1 Mrs. Tinlin, had you had any occasion, that you
2 recall, to call Bard for information about this
3 filter before you placed it in Ms. Tinlin?

4 A. No.

5 Q. Do you ever recall making any contact
6 with Bard --

7 A. No.

8 Q. -- for the purpose of trying to obtain
9 additional information regarding their filters?

10 A. No.

11 Q. At the time that you placed the filter in
12 Ms. Tinlin, would you have had any discussions with
13 her about potential retrieval of the filter?

14 A. I can't remember.

15 Q. Is that something that you typically
16 discuss?

17 A. Yes.

18 Q. And what do you typically tell your
19 patients about potential retrieval of a retrievable
20 filter?

21 A. In discussing, during the consent time,
22 if we're going to place a retrievable filter, we
23 would -- I would simply say that if we need to take
24 this out and we're able to take it out, in general,
25 it can be removed.

1 Q. Do you also typically tell your patients
2 that the filter might be left permanently even
3 though it's a retrievable filter?

4 A. Yes.

5 Q. And it sounded like you also tell your
6 patients that even though it's a retrievable
7 filter, that there's a probability that it might
8 not be able to be retrieved?

9 A. Correct.

10 Q. And do you believe that you would have
11 had such discussions with Mrs. Tinlin?

12 A. Most likely, yes.

13 Q. Let's take another look at the consent
14 form, which is in the Exhibit 929. Do you have
15 that in front of you?

16 A. Yes.

17 Q. And I know, in answering questions from
18 counsel for Mrs. Tinlin, you've sort of explained
19 what you normally discuss with patients before you
20 place filters. I just have a few more questions
21 about this. Do you recall either Mrs. Tinlin, or
22 anyone else who may have been present, making any
23 questions of you -- or asking any questions of you
24 regarding this filter?

25 A. No.

1 the cause of any of her pain?

2 A. I would not have been asked to, nor would
3 I have attempted to. I should clarify that by
4 saying we're asked to render opinions on images.
5 And the doctors who order the images, they take all
6 that information with the clinical and they make
7 diagnoses with our assistance. We're a consultant.

8 Q. So as far as diagnosing what was causing
9 any pain that Mrs. Tinlin was experiencing, am I
10 correct that that is not something that you would
11 do?

12 A. I assist the doctors who are actually
13 taking care of the patient. The example would be
14 if someone has a possible appendicitis and they
15 order a CAT scan, I might say I see appendicitis,
16 but that's doesn't mean that's what they have. I
17 don't have the final word. They put in clinical
18 data: does the patient have a fever, are the labs
19 abnormal, and the final say is actually if they
20 undergo operation would be the pathologist, was the
21 appendix inflamed or not. So we render opinions on
22 images, but that has to go with the clinical
23 information as well.

24 Q. And as far as any conclusions that you
25 ever came to regarding Mrs. Tinlin, those would be

1 lungs is quite useful.

2 Q. As you sit here today, do you see any
3 reason that you would not have agreed with
4 Dr. Andrews as far as leaving the Recovery filter
5 in as a permanent filter?

6 A. No.

7 Q. Dr. Riebe, I believe there was an exhibit
8 that I failed to ask you some questions about so
9 far. It's Exhibit 920. It was one of the Bard
10 documents that you were shown.

11 A. Yeah, the Wayback Machine. 920.

12 Q. Yes. It should say at the top health
13 hazard evaluation.

14 A. Yes.

15 Q. Do you know what a health hazard
16 evaluation is?

17 A. No.

18 Q. And are you familiar with the assessment
19 processes that a medical device company goes
20 through in looking at complications or issues with
21 their products?

22 A. No.

23 Q. In looking at this exhibit that was shown
24 to you, would it appear to you that Bard is
25 actively investigating the events described in this

1 Q. Okay. I have such a protective order
2 here with me, and I'll -- when we go off the
3 record, I'll ask you to take a look at it and sign
4 it. And then --

5 A. I should -- if I have to sign two inches'
6 worth, then I'm not going to sign. That's a big
7 stack.

8 Q. No, that's not it. It's right here, if
9 you want to look at it.

10 MR. GOLDENBERG: Can we do this after?

11 MS. DAVIS: Sure, yeah. But this is it.

12 THE WITNESS: Okay. This is --

13 MS. DAVIS: But yes, we can do it after
14 the deposition. Absolutely. I don't have any more
15 questions at this time.

16 THE WITNESS: Okay.

17 MS. DAVIS: Thank you, Doctor.

18 E X A M I N A T I O N

19 BY MR. GOLDENBERG:

20 Q. I just have a few.

21 A. Okay.

22 Q. Doctor, again, Stuart Goldenberg. I just
23 wanted to ask you, when you are talking with the
24 patient about the risks and benefits of a device
25 like the Bard IVC filter, the Recovery, you can

1 only convey what you know; correct?

2 A. Correct.

3 Q. All right. If a company is hiding
4 important safety information, there's no way for
5 you to know that, is there?

6 A. Correct.

7 MS. DAVIS: Object to the form.

8 BY MR. GOLDENBERG:

9 Q. I think we're all making an assumption
10 here that vena cava filters can prevent blood
11 clots. Is that your understanding?

12 A. No, the vena cava filters can prevent
13 clots from moving to places where you don't
14 necessarily want them.

15 Q. Good -- good point. And what's the basis
16 for that?

17 A. It's a mechanical basis.

18 Q. But what medical studies are you aware of
19 that show that?

20 MS. DAVIS: Could you let him finish his
21 answer?

22 THE WITNESS: I'm not -- I'm not -- I
23 don't know specific studies.

24 BY MR. GOLDENBERG:

25 Q. Are you aware that there has been a great